DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Indian Health Service
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INDIAN HEALTH SERVICE CIRCULAR NO. 95-03

ORGAN TRANSPLANTATION MANAGEMENT

Sec.
1. Purpose
2. Background
3. Definitions
4. Policy
5. Procedures
6. Effective Date

1. Purnose. To establish the Indian Health Service (IHS) policy regarding the management of major organ transplantation cases. This circular shall be used in conjunction with the 1992 Administrative Guidelines for the IHS Catastrophic Health Emergency Fund (CHEF) and the Indian Health Manual, Part 2, Chapter 3, entitled l'Contract Health Services."

2. Background. The IHS has limited resources for meeting the health care needs of the American Indian and Alaska Native population, particularly in the Contract Health Services (CHS) program. Major organ transplantation therapy has become more accessible and acceptable to American Indian and Alaska Native beneficiaries served by the IHS. Currently 7-10 percent of the CHEF is being utilized for major organ transplantation therapy. In an effort to maximize the buying power of CHS, the IHS has implemented a more structured form of managed care to reduce costs and enhance quality. One aspect of managed care is High Cost Case Management (HCCM) which addresses those episodes of care that have the potential of becoming CHEF cases. The HCCM is the process by which the IHS attempts to obtain an optimal quality of care and patient outcome while containing costs, maximizing services within available resources, and enhancing communication and cooperation with non-IHS providers of health care. Major organ transplantation therapy is a specialized component of HCCM.

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3. Definitions.

A. CHEF Case - An episode of acute medical care for a condition from an illness or injury, requiring extensive treatment, that incurs major medical costs to the IHS in excess of the CHEF threshold,

B. CHEF Threshold Cost - A designated amount above which incurred medical costs will be considered for CHEF for CHEF reimbursement after a review of the authorized expenses and diagnosis.

C. Centers of Excellence - A facility or institution that has met or exceeded defined standards of care for the specific procedure in question and has entered into a formal contractual agreement with the IHS.

D. Episode of Care - The period of consecutive days for a discrete health condition during which reasonable and necessary medical services related to the condition occur.

E. Major Organ Transplant - For the purposes of this policy, organ transplantation will refer only to major organ transplants approved for Medicare funding by the Health Care Financing Administration (HCFA). Currently this includes heart, liver, lung, kidney, and bone marrow.

E. Medical Selection Criteria - A series of factors that identify individuals who are potential candidates for major organ transplantation. The IHS has distributed Agency medical selection criteria for heart,. liver, lung,, and bone marrow transplants.

4. Policy.

A. The IHS shall provide resources from the CHS Program for major organ transplantation procedures that have been approved by HCFA for funding under the Medicare program. Presently, this includes heart, kidney, liver, lung and bone marrow transplants.

(1) For liver and bone marrow transplants, CHS funds will only be authorized for conditions approved by HCFA.

(2) For liver and heart transplants, CHS funds will be authorized only for patients referred to medical centers that have received HCFA certification of their liver or heart transplant program. The use of HCFA certified transplant programs for any other type of organ(s) will be required only if HCFA publishes a national policy regulation covering the other organ(s).

(3) The majority of kidney transplants are funded through the Medicare End-Stage Renal Disease Program. Payment for deductibles, co-payments and immunosuppressant medication may be authorized through the CHS program, and may qualify for CHEF.

B. The IHS shall perform HCCM on every CHS extra-renal major organ transplantation patient, since all have the potential of becoming a CHEF case. The objective is to establish an uniform procedure for organ transplantation therapy management to maximize quality care and cost effectiveness. The process shall respect the patient's unique needs, cultural factors, and environment. The IHS recommends that all Tribally contracted health care programs also implement this policy.

C. Organ transplantation case management includes the certification, monitoring, and management of services during the pre-transplant evaluation phase, the transplant surgical phase, and the post-operative follow-up period. The CHEF reimbursement is available to Area CHS programs for expenditures on eligible patients who incur extraordinary medical costs.

(1) The patient must be eligible for IHS services and must meet the current regulations and policies of the CHS program.

(2) Reimbursements will be considered only for allowable costs above the threshold and only after cases are reviewed and approved by the Fund manager.

(3) No payment shall be made from the CHEF to any provider to the extent that such provider is eligible to receive payment for treatment from any other Federal, State, local, or private source of reimbursement for which the patient is eligible.

D. Post Tranplant Care.

(1) Post-operative-care in support of the transplant will be considered an essential component of the patient's care and may be included as part of the Episode of Care for the purposes of reimbursement from the CHEF. Approved post-operative care includes necessary support services such as psychological, social services, housing, etc.

(2) Funds for on-going immunosuppressant medications are to be considered a necessary expense for the continued well being of the post-transplant patient. These drugs may be considered a component of the Episode of Care for the purposes of reimbursement from the CHEF.

(3) Admissions for late major complications (generally 120 days after the initial transplant) and re-transplants will be considered a new episode of care and should be prioritized on an individual basis. Standard CHS operating procedures will be followed in order to determine the appropriateness of care and the medical priority of the *service.*

E. Centers of Excellence COE).

(1) To the extent possible, the IHS will identify and negotiate agreements with COE for patients requiring extra-renal major organ transplantation.

(2) All identified COE will have a national or regional agreement with the IHS. The award will be based on but not limited to the following:

a. demonstrated quality of care;

b. facility certification by an organizational entity such as HCFA *or* the Joint Commission on Accreditation of Healthcare Organizations (for heart and liver transplants, HCFA certification is a requirement);

c. adequate case load (as determined by HCFA, where applicable);

d. agreement to provide appropriate follow-up and field consultation;

e. support services (housing, local transportation, psychological, and social *services),;*

f. demonstrated experience in dealing with divergent cultural, socio-economic, and spiritual backgrounds; and

g* cost.

(3) If a COE determines that an IHS patient does not qualify for an *organ* transplant', then CHS funds can not be used to pay for that transplant at any other facility not designated as an COE.

(4) Use of COE

a. When available the use of IHS COE for patients requiring extra-renal major organ transplantation is mandatory, except as noted in b. and c. below.

b. The mandatory *use* of COE applies to those situations when the IHS is the predominate payor. Patients with predominant alternate resource coverage may be referred to other than an IHS COE at the discretion of the referring physician, in accordance with the policies of the alternate resource payor. The use of the COE with coordination of benefits between IHS and the alternate resource is encouraged.

c. Under these additional circumstances, patients need not be referred to a COE:

(i) The life of the patient would be jeopardized by a distant transfer; or

(ii) The patient's disease process requires a specific expertise that is not available at the COE facility; or

(iii) The IHS has not yet established a contractual relationship with a transplant center for the involved organ.

5. Procedure.

A. Service Unit.

(1) The provider identifies a patient who is a potential candidate for a major organ transplant.

(2) The service unit CHS Committee reviews the case and determines the patient's CHS eligibility, the medical priority of the case, the extent of alternate resource coverage, and whether or not the potential transplant can be approved according to established clinical criteria. The committee, in consultation with the patient's physician(s) determines if the patient should be referred for 'evaluation to a COE or whether the patient meets one or more of the exceptions (see 4.E.4.).

(3) The Area CHS Officer and Area Chief Medical Officer (CMO) are notified in cases where the IHS will be the predominate or full payor.

(4) If appropriate, the referral for the evaluation is made. If an IHS partial or full-pay patient meets one of the exceptions to the use of a COE, the service unit must have Area CM0 written concurrence before referring the patient to another institution.

(5) Once the authorization and referral for the evaluation is made, the CHS Committee will follow CHEF High Cost Case Management Guidelines for all cases.

(6) If the COE determines that a transplant is necessary and the patient meets the clinical criteria established by the COE, then the service unit must process a second CHS authorization and referral for the transplant procedure.

(7) The local IHS providers responsible for the patient will ensure appropriate local follow-up of all cases in consultation with the COE and other local consultants.

(8) The local service unit will be responsible for ensuring that transportation is arranged for the patient, including an escort, from the patient's area of residence to and from the major airport nearest the transplant center.

(9) In the event that a service unit wishes to appeal for CHS coverage of an unapproved transplant procedure, refer to IHS Circular 93-03, entitled "Cosmetic and Experimental Procedures," Section 5.B.

B. Area Office.

(1) The Area CHS Officer ensures that proper procedure is being followed.

(2) The Area CHS Officer notifies the IHS Headquarters CHEF manager regarding all referrals **and** reports the necessary information to the Headquarters CHS Branch.

(3) The Area CM0 approves all referrals in writing (both for evaluations and transplants), with the exception of patients predominately covered by alternate resources. If necessary, the Area CM0 authorizes a written exception to the COE policy, under 4.E.4 above. A copy of this exception will be sent to the Headquarters CHS Branch. Under emergency situations, the approval process must be performed in an expeditious manner.

c. HeadQuarters.

(1) The IHS Headquarters, Office of Health Programs (OHP) is responsible for the development, negotiation, . and maintenance of formal agreements with the COE.

(2) The IHS Headquarters, OHP will distribute to all Area CHS Officers a listing of the designated center(s) once the agreement(s) has/have been established.

(3) Headquarters OHP will monitor the use of the COE. An annual report (in consultation with the involved service units and the fiscal intermediary) will be prepared for Area CMOs, Area CHS officers, and the clinical advisory group that will evaluate:

a. volume and distribution of referrals;

b. outcome of cases;

c. waiting time;

d. patient acceptance;

e. alternate resource payor cases; and

f. the IHS costs.

(4) Headquarters CHS will monitor the frequency of exceptions to the policy and report annually to the Area CMOs and the clinical advisory group.

6. Effective date. This policy will become effective on the date of signature. Referrals to designated IHS transplant COE will be a requirement on the date specified by the negotiated contract(s).

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